

REMARKS

The Applicant respectfully requests the Examiner to address all correspondence to the indicated address of the undersigned. The Examiner is referred to the Power of Attorney and related documentation submitted with the Applicant's Amendment of October 29, 2004 (in response to the Office Action of July 30, 2004).

Claims 1, 4-7, 9-10, 12-14, and 45 are pending.

A Notice of Appeal is respectfully submitted herewith.

I. The Applicant respectfully highlights the Written Description of the invention, as claimed, at page 26, lines 1-4, *inter alia*, reproduced as follows:

"The invention relates generally to the *in-situ* monitoring of an amplification reaction of one or more biomolecules using a multisensor array (MSA) or at least one sensor with several possible physical and/or chemical responses for detecting some volatile compounds." Emphasis added. The Applicant moreover, respectfully submits, that the meaning of the term "in-situ" is well-known to those of ordinary skill in the arts of biology and chemistry, i.e., something that is in its original place, unmoved; confined to the site of origin. The instant Written Description refers to an exemplary physical embodiment of a means to accomplish the described method as follows:

FIG. 1's entire assembly 10 shows the physical components that preferably may be assembled in realization of the present invention ... Typically, a container [i.e., reaction vessel] 24 contains at least one medium 26 (e.g., liquid) with reagents 28 (e.g., enzymes, primers, one or more of the four deoxyribonucleotide 5' triphosphates (dNTP's), water and typical sub-components of a PCR reaction mixture) and at least one biomolecule 30, preferably a target DNA template.

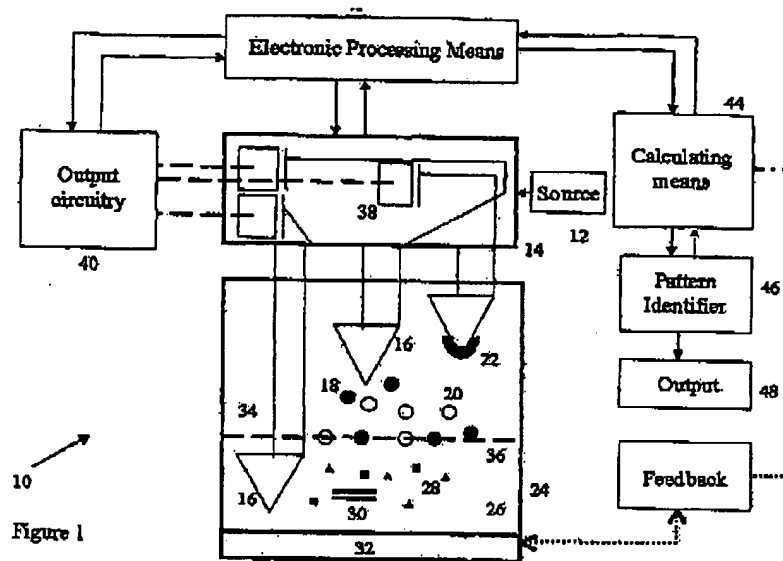


Figure 1

The container 24 can also be thermally regulated with a thermal cycler bloc 32 (e.g., Peltier element) which can help convert at least one part of the sample into preferably a gas phase or headspace 34. The sample is preferably passed through a transmission element 36 (e.g., membrane or semi-permeable membrane) where various components 18 and 20 representative of the advancement of the PCR amplification reaction can be delivered to at least a proximity of a probe 16.¹ Emphasis added. Since the language of claim 1 literally requires **direct *in-situ* monitoring of the reaction**, the claim unambiguously refers to the monitoring of products of the reaction at the site of the polymerase reaction, i.e, in the reaction vessel, in real-time during the reaction.²

The Applicant respectfully submits that Written Description, as required by the statute, accordingly exists in the original disclosure. The Applicant accordingly respectfully requests the Examiner to withdraw the outstanding rejections under 35 USC §112.

¹ Page 28, lines 1-3. Page 28 line 21- page 29, line 4.

² The Applicant further points to the language of lines 12-17, i.e., "[b]ecause of the novelty of the present embodiment, some of the severe constraints relative to the use of fluorescent labels (e.g., requiring four spectrally resolvable dyes, photobleaching, quantum efficiency, etc.) can be overcome by employing any volatile compound either consumed in a reaction, and/or producing by-products ...". See, also, the ABSTRACT OF THE DISCLOSURE; as well as the language, at page 15, lines 22- page 16, line 11, for example.

II. Since the claims now pending require *in situ* monitoring, i.e., positioning the multisensor array and screening the medium in the same container (i.e., reaction vessel) as a nucleic acid polymerase reaction, particularly in view of the Written Description and the reference to FIG.1, the disclosure of Van Ness cannot anticipate as a matter of law.

The Applicant respectfully point out that the Van Ness '893 disclosure provides a method for sequencing nucleic acids that fundamentally and necessarily requires, *in the order*, 1) separation of nucleic acids from the reaction vessel, 2) cleavage of a tag from the nucleic acid, and 3) detection of the tag. "Following separation of the tagged fragments by sequential length, the tags are cleaved from the tagged fragments. In a preferred embodiment, the tags are detected by mass spectrometry and the sequence of the nucleic acid molecule is determined therefrom." The requirement is unequivocally illustrated globally throughout the specification as well as in Van Ness' FIG.15-16 highlighted by the Examiner.

Since all subject matter of the instant claims now pending is limited to a method for *directly* monitoring a *polymerase reaction*, i.e. interrogating (probing) the medium *in situ*, i.e., in the reaction vessel, *during* the reaction, none of the claims presented herewith encompass anything within the disclosure of Van Ness '893.

The Applicant accordingly respectfully requests the Examiner to withdraw all rejections under 35 USC §102.

III. Since none of the references cited by the Examiner disclose, suggest or contemplate a method for *directly* monitoring a nucleic acid *polymerase reaction*, i.e. interrogating (probing) the medium *in situ*, i.e., within the reaction vessel *during* the reaction, the presently claimed subject matter cannot be obvious as a matter of fact in view of the Federal Circuit's interpretation of the statutory requirement for patentability.

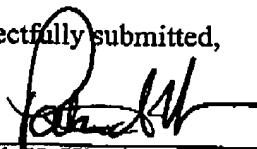
The Applicant accordingly respectfully requests the Examiner to withdraw all rejections under 35 USC §103.

For all the foregoing reasons, the Applicant submits that Claims 1, 4-7, 9-10, 12-14, and 45 are in condition for allowance. Early action toward this end is courteously solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution.

Respectfully submitted,



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